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			JOHANNSEN, DIANA B	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/821.805 STENDER, HENRIK Office Action Summary Examiner Art Unit Diana B. Johannsen 1634 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 02 September 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.5-11.25 and 34-37 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1,5-11,25 and 34-37 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

information Disclosure Statement(s) (PTO/S5/06)
 Paper No(s)/Mail Date ______.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 2, 2009 has been entered.

Claims 1, 25, 34, and 36 have been amended. Claims 1, 5-11, 25, and 34-37 remain under consideration herein.

Claim Rejections - 35 USC § 112, second paragraph

- It is noted that applicant's amendments have overcome the rejections under 35 USC 112, second paragraph of claims 1, 5-11, and 25 set forth in the prior Office action of May 20, 2009.
- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant repards as his invention.
- 4. Claim 1, 5-11, 25, 34, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-11, 25, 34 and 36 are indefinite over the recitation of the language "said PNA probe comprises a sequence of 15-17 nucleobase subunits in length". It is clear from this claim language that the claimed probes must include a minimum of 15 nucleobase subunits; however, the inclusion of the upper limit of 17 nucleobases is

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confusing given the use of the open transitional language "comprising". More particularly, the recitation "15-17 nucleobase subunits in length" suggests that applicant may intend to limit the length of the claimed probes to 17 subunits; however, the use of the open transitional language "comprising" suggests that any number of additional nucleobase subunits may be included (assuming the other requirements of the claims are met). Accordingly, the language "comprises a sequence of 15-17 nucleobase subunits in length" is confusing and does not clearly apprise one of skill in the art as to what types of structures would or would not infringe the claimed invention. Clarification is therefore required.

Claim 36 as amended is drawn to "The PNA probe of claim 34, and instructions for use". It appears that applicant may have misunderstood the language being suggested by the examiner in the prior Office action (as other language suggested by the examiner has been adopted); the language actually being suggested was: "A kit comprising the PNA probe of claim 34 and instructions for use" (i.e., the examiner intended to suggest replacing the indefinite portion of the claim language with the language "the PNA probe of claim 34 and instructions for use"). The claim as presently written does not make clear the nature of the invention being claimed; for example, is the claim drawn to a composition or a kit comprising the 2 recited reagents, or are the 2 recited components part of a single structure, etc.? Clarification is required with regard to the nature of the product being claimed. This rejection could be overcome by amending the claim as indicated above (i.e., to recite: : "A kit comprising the PNA probe of claim 34 and instructions for use").

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Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1, 5-7, 9-11, 34-35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ludwig et al (Applied and Environmental Microbiology 60(9):3236-3244 [9/1994]) in view of Hyldig-Nielsen et al (US 6,169,169 B1 [01/2001]).

It is noted that all of the instant claims encompass PNA probes comprising the preferred sequence SEQ ID NO: 1. Claims 35 and 37 specifically recite such a probe. Independent claims 1 and claims dependent therefrom embrace a probe wherein "at least a portion" is "at least 90% identical to" SEQ ID NO: 1 or the complement thereof. Independent claim 34 recites a probe that "comprises" SEQ ID NO: 1, "the complement or variations thereof". Each of claims 1 and 34 state that the claimed probe "comprises a sequence of 15-17 nucleobase subunits in length" (it is again noted that this language is indefinite for the reasons given above). It is also noted that the specification teaches that the sequence SEQ ID NO: 1 is present in each of the Pseudomonas species recited in independent claims 1 and 34 (see, e.g., Table 1).

Ludwig et al disclose 23S rRNA partial sequences for a variety of Pseudomonas species, each of which includes an RNA sequence corresponding to the reverse complement of instant SEQ ID NO: 1 (see entire reference, particularly Figure 2); thus,

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Ludwig et al inherently disclose that instant SEQ ID NO: 1 exactly complements the 23S rRNA sequence of a variety of pseudomonads. It is also noted that an inspection of Figure 2 of Ludwig et al reveals that there are sequence differences between all pseudomonads and a variety of other bacterial species at the region corresponding to instant SEQ ID NO: 1 (see Figure 2). Thus, the teachings of Ludwig et al suggest that the region of 23S rRNA corresponding to instant SEQ ID NO: 1 is a suitable target for a genus-specific probe for pseudomonads. However, Ludwig et al do not teach a PNA probe comprising SEQ ID NO: 1.

Hyldig-Nielsen et al disclose PNA probes targeting the 23S rRNA or rDNA sequences of Neisseria gonorrhoeae and Chylamydia trachomatis (see entire reference). Hyldig-Nielsen et al disclose that probe sequences are selected that will hybridize to and identify target organisms of interest (see, e.g., col 4, line 55-col 5, line 24). Hyldig-Nielsen et al further disclose that PNA probes are advantageous as compared to DNA probes for a variety of reasons, e.g., because shorter probes may be used in sensitive assays, because PNA probes "allow greater flexibility in" assay format, and because hybridization can occur "under conditions not favorable for ordinary DNA probes" (see col 2, lines 37-57).

In view of the teachings of Ludwig et al and Hyldig-Nielsen et al, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have prepared a PNA probe comprising SEQ ID NO: 1 for use in detecting one or multiple Pseudomonas species. As noted above, Ludwig et al disclose that SEQ ID NO: 1 is the exact complement of 23S sequences of a variety of pseudomonads, and

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that it is not the exact complement of a variety of other species. Hyldig-Nielsen et al suggest selecting such complementary sequences for use in detecting target sequences of interest, and further suggest a variety of advantages of PNA probes as compared to DNA probes. Thus, an ordinary artisan would have been motivated to have prepared such a probe for the advantage of, and to achieve the predictable result of, preparing a PNA probe that could be used successfully in the specific detection of pseudomonads in a variety of assay formats and hybridization conditions, as suggested by the teachings of Ludwig et al and Hyldig-Nielsen et al. It is also noted that the product suggested by Ludwig et al in view of Hyldig-Nielsen et al could be used by one of skill in the art in a variety of methods "for the detection, identification and/or quantitation of Pseudomonas".

Regarding claims 5-7, Hyldig-Nielsen et al suggest a variety of different labels that may be used successfully with PNA probes (see, e.g., col 8, line 19-col 9, line 57), including, e.g., fluorophores, enzymes, conjugates, haptens, luminescent labels, etc. (see col 8, lines 38-41, teaching multiples labels encompassed by claim 6). With further regard to claim 7, it is a property of many of the labels of Hyldig-Nielsen et al that they may be used in such a way as to be "self-reporting," such that the requirements of the claim are met. (It is noted that the specification teaches at page 9 that beacon probes are simply "examples" of self-indicating probes; thus, the instant claim is not limited to this particular type of self-reporting probe). With regard to claim 9, Hyldig-Nielsen et al also teach unlabeled PNA probes (see, e.g., col 9, line 58-col 10, line 28). Regarding claim 10, Hyldig-Nielsen et al teach PNA probes bound to a solid support (see, e.g., col

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19, lines 10-50). Regarding claim 11, Hyldig-Nielsen et al also teach the use of linkers in PNA probes (see. e.g., col 8, lines 19-36 and col 10, lines 29-41).

With regard to claims 35 and 37, it is again noted that Ludwig et al and Hyldig-Nielsen et al suggest PNA probes comprising SEQ ID NO: 1, which probes are specifically recited by these claims.

With further regard to claim 37, requiring a PNA probe comprising SEQ ID NO: 1 in a kit, it is noted that Hyldig-Nielsen et al teach kits comprising PNA probes "for use in diagnostics" employing the probes (see, e.g., col 20, lines 1-12). In view of the teachings of Hyldig-Nielsen et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have to have packaged the probes suggested by Ludwig et al and Hyldig-Nielsen et al, including a PNA probe comprising instant SEQ ID NO: 1, in a kit. An ordinary artisan would have been motivated to have made such a modification because Hyldig-Nielsen et al specifically suggests preparing such kits comprising PNA probes "for use in diagnostics."

The response of September 2, 2009 traverses the prior rejection of the instant claims using the same combination of references on the following grounds.

The reply argues that the Ludwig reference "fails to teach or suggest all the elements of the instant invention," and particularly that Ludwig "does not teach or suggest a single nucleobase sequence as a suitable target for a genus specific probe for the detection, identification or quantitation of Pseudomonas". The reply urges that Ludwig et al do not teach or suggest a PNA probe that is "complementary to

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a target sequence of 23S rRNA or rDNA of the species of the genus of Pseudomonas as instantly claimed." The reply summarizes Ludwig et al's teachings of "comparative sequence analyses of bacterial 23S rRNA genes" and a generated alignment of bacterial 23S rRNA sequence. The reply also summarizes the examiner's previous response to applicant's arguments, with which applicant disagrees. The reply notes that applicant has identified a genus-specific probe, and that the Lugwig reference "nowhere teaches or suggests one specific region of 23s rRNA that is suitable for the detection. identification or quantitation of Pseudomonas". The reply urges that "Lugwig does not provide any guidance or suggestion that there is one specific probe that detects one specific region", and further that "the art teaches that no one probe to one specific region of 23s rRNA is known or suggested that can suitably detect, identify or quantitate the genus of Pseudomonas." The reply also references a different reference of Hyldig-Nelsen et al (US 6,664,045), arguing that this references teaches that a set of 3 probes were required to detect the genus pseudomonas, and that "no one probe to one specific region of 23s rRNA is known or suggested that can suitably detect, identify or quantitate the genus of Pseudomonas". The reply further argues that the Ludwig reference teaches only 4 non-pseudomonads, and asserts that the teachings of Ludwig are insufficient to allow one to determine a region for use as a genus specific probe. Finally, the reply argues that Hyldig-Nielsen et al "does not cure the defects" of Ludwig and does not teach the PNA probes of the claims.

These arguments have been thoroughly considered but are not persuasive.

It is again noted that the instant claims are not drawn to, e.g., a method via which any of

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the recited species may be identified (i.e., a method that specifically detects the genus Pseudomonas); rather, the claims are drawn to probes having particular properties. As the combined teachings of Ludwig et al and Hyldig-Nielsen et al suggest probes having the structure of applicant's preferred PNA probe (i.e., comprising instant SEQ ID NO: 1), the references suggest the invention being claimed. The sequence suggested by the references is the exact, preferred sequence claimed by applicants; accordingly, any functional properties recited in applicant's claims are inherently present in the sequence suggested by the references. The fact that the claims recite additional properties that may have been unknown or unappreciated in the prior art cannot render patentable the claimed product, which is structurally identical to that suggested by the art. See MPEP 2112, which states::

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >

and further states that:

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPC2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPC2d 1584, 1590 (Fed. Cir. 2004)("T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51 USPC2d 1307, 1310 (Fed. Cir. 1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not

the parties to the transaction recognize that the product possesses the claimed characteristics."): Atlas Powder Co. v. Ireco. Inc., 190 F.3d 1342, 1348-49 (Fed. Cir.

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1999) ("Because sufficient aeration" was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention... An inherent structure, composition, or function is not necessarily known.")>: Smithkline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1349-44, 74 USPQ2d 1398, 1400-607 (Fed. Ci. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemithydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate!>.

Further, MPEP 2112.01 states that:

or rDNA sequences of each species recited in the claims.

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior and teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPO2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelly.").

attempting to rely in obviating the present rejection (e.g., the "genus-specific" nature of the probe, the intended use in detection, identification, etc.) are simply inherent characteristics. Further, as was previously noted, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). It is also again noted that the claims are not limited to the preferred structure of SEQ ID NO: 1. Regarding the issue of complementarity, it is an inherent feature of SEQ ID NO: 1 (i.e., the sequence suggested by the references) that it is complementary to 23S rRNA

In the present case, the structure embraced by the claims and the structure suggested by the prior art are in fact identical: the properties on which applicant is

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Regarding applicant's argument that the Ludwig reference teaches only 4 non-pseudomonads, and that the teachings of Ludwig are insufficient to allow one to determine a region for use as a genus specific probe, it is reiterated that the claims are directed to the probe itself (not to, e.g., a new and unpredictable use of that probe), and therefore do not require that the probe of the claims be employed in a particular way or to achieve a particular goal. The cited references suggest a PNA probe comprising instant SEQ ID NO: 1, and therefore are sufficient to meet the requirements of the rejected claims.

Finally, regarding applicant's argument that Hyldig-Nielsen et al "does not cure the defects" of Ludwig and does not teach the PNA probes of the claims, it is again noted that the instant rejection relies on the combined teachings of the references. Hyldig-Nielsen et al was cited for its teachings with regard to the selection of target sequences for probes, and the advantages of PNA probes over other types. It is unnecessary for Hyldig-Nielsen et al to provide teachings or guidance that were provided by the Ludwig reference. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

7. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ludwig et al in view of Hyldig-Nielsen et al, as applied to claims 1, 5-7, 9-11, 34-35, and 37, above, and further in view of Gildea et al (US 6,485,901 B1 [26 November 2002; filed 26 October 1998]; cited in the IDS of November 2004]).

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This rejection applies to claim 7 to the extent that it may be drawn to the particular type of self-reporting probe of claim 8 (i.e., to linear beacon probes).

The teachings of Ludwig et al and Hyldig-Nielsen et al upon which this rejection relies appear above in paragraph 6. While Hyldig-Nielsen et al teach PNA probes labeled at opposite ends with different fluorophores (see, e.g., col 11, lines 26-35), Lugwig et al and Hyldig-Nielsen et al do not specifically suggest PNA linear beacons as set forth in claim 8.

Gildea et al disclose that PNA linear beacons are "particularly well suited" for "detection, identification or quantitation" of target sequences in closed tube assays, asymmetric PCR, and in living or non-living cells, tissues and organisms (because the beacons are not degraded by enzymes) (see entire reference, particularly col 9, lines 31-58). In view of the teachings of Gildea et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the PNA probes suggested by the teachings of Ludwig et al in view of Hyldig-Nielsen et al to have included the donor and acceptor moieties required to form PNA linear beacon probes, as suggested by Gildea et al. An ordinary artisan would have been motivated to have made such a modification for the advantage of preparing a probe well-suited for any of the assays noted above, as specifically suggested by Gildea et al.

The reply of September 2, 2009 traverses the rejection on the same grounds discussed above in paragraph 6 regarding the combination of Ludwig et al and Hyldig-Nielsen et al. Accordingly, the response to those arguments applies equally herein.

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 Claims 25 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ludwig et al in view of Hyldig-Nielsen et al, as applied to claims 1, 5-7, 9-11, 34-35, and 37, above, and further in view of Ahern et al (The Scientist 9(15):20 [July 1995]).

It is noted that claim 36 has been interpreted as requiring a composition or kit comprising the materials recited in the claim (the claim is indefinite for the reasons noted above).

The teachings of Ludwig et al and Hyldig-Nielsen et al upon which this rejection relies appear above in paragraph 6. It is again noted that Hyldig-Nielsen et al teach kits comprising PNA probes "for use in diagnostics" employing the probes (see, e.g., col 20, lines 1-12), such that the combined teachings of Ludwig et al and Hyldig-Nielsen et al suggest kits comprising the probes suggested by the two references. Further, as the kits suggested by Ludwig et al in view of Hyldig-Nielsen et al could be used in any of the assays mentioned in claim 25 (i.e., for any of the recited intended uses of the probes/kits), the references suggest all of the limitations of the claimed kits with the exception of the "instructions for use" as recited in the claims.

Ahern teaches that premade reagents provided in kit form are convenient and save researchers time and money, and further teaches the inclusion in kits of "detailed instructions to follow" (see p. 4/6). In view of the teachings of Ahern, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the kits suggested by Ludwig et al and Hyldig-Nielsen et al so as to have included therein instructions for use of the enclosed reagents. An ordinary artisan

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would have been motivated to have made such a modification in order to have allowed an artisan to more readily use the reagents in a correct manner, thereby saving the practitioner time and reagents, as suggested by the teachings of Ahern.

The reply of September 2, 2009 traverses the rejection on the same grounds discussed above in paragraph 6 regarding the combination of Ludwig et al and Hyldig-Nielsen et al. Accordingly, the response to those arguments applies equally herein.

Conclusion

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Diana B. Johannsen whose telephone number is
571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30
am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571/272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Diana B. Johannsen/ Primary Examiner, Art Unit 1634